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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,086	BASKIN ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-67* is/are pending in the application.

4a) Of the above claim(s) *51-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed 6/22/2006 to the Office action has been entered. Claims 26-67 are pending.

1. Claims 26, 28-35, 39-40, 43-45 and 47-50 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wittwer et al. (6,174,670, issued January 16, 2001).

Wittwer et al. disclose the method of monitoring hybridization during polymerase chain reaction using of double stranded DNA dye or specific hybridization probes and quantitating amplified DNA (See the Abstract). The invention of Wittwer et al. includes a method of detecting a difference at a selected locus in a first nucleic acid as compared to a second nucleic acid (See column 8, lines 35-37). The method comprises providing a pair of primer for amplification by polymerase chain reaction and an oligonucleotide probe, wherein one of the primers and the probe are each labeled with one member of a fluorescence energy transfer pair comprising an donor fluorophore and an acceptor fluorophore (See column 8, lines 38-58). The selected segment of first nucleic acid and the corresponding segment of the second nucleic acid are amplified by polymerase chain reaction in the presence of effective amounts of primers and probe to result in an amplified selected segment and an amplified corresponding segment, at least a portion of having the labeled primer and probe hybridized thereto with fluorogenic resonance energy transfer pair in resonance energy transfer relationship (See column 8, lines 59-67). The amplified segments are illuminated, fluorescence emission is measured by a device (See column 22, lines 59-66), the first melting profile of the probe melting from the amplified selected segment of the first nucleic acid and a second melting profile of the probe melting from the amplified selected segment of the second nucleic acid are determined. The first melting profile to

the second melting profile is compared to determine the differences between these segments (See column 9, lines 1-15). The fluorescent indicator is SYBR™ Green I, ethidium bromide (See column 22, lines 54-56) and a 5'-nuclease probe (See column 17, lines 22-26). The nucleic acid is from human genomic DNA (See column 26, lines 29-30).

Wittwer et al. do not explicitly disclose combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide.

Wittwer et al. disclose that three fluorescence-monitoring techniques for PCR are performed. Each reaction composition has a pair of primers and a fluorescence indictor (See column 32, lines 28-61). It is inherent in this teaching that the nucleic acid sample combined at least one set of reaction compositions comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide. Thus the teachings of Wittwer et al. anticipate the limitations of the claims.

The response argues that the Examiner failed to address the language when discussing Wittwer regarding the limitations "combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction

composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide" which is not explicitly taught by Wittwer. [redacted] Witter disloses that three fluorescence-monitoring techniques for PCR are performed. Each reaction composition has a pair of primers and a fluorescence indictor (See column 32, lines 28-61). It is inherent that there are at least two reaction compositions in which each composition has amplification primers specific to the at least one target polynucleotide and a fluorescent indicator. Thus the teachings of Wittwer read on the limitations recited in the claims. Therefore, the rejection is maintained.

2. Claims 27, 36-38 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. (6,174,670, issued January 16, 2001) as applied to claims 26, 28-35, 39-40, 43-45 and 47-50 above, and further in view of Johston-Dow et al. (6,103,465, issued August 15, 2000).

The teachings of Wittwer et al. are set forth section 3 above. Wittwer et al do not disclose a nucleic acid sequencing reaction on the amplification product, the source of DNA sample used as listed in claims 36-38 and determining at least one HLA type.

Johnston-Dow et al. disclose a method for typing HLA class I gene and the method involving DNA sequencing techniques (See the Abstract and column 9, lines 9-22). The method is to provide for the specific DNA sequencing of HLA-A, HLA-B and HLA-C (See column 3, lines 19-22). Johnston-Dow et al. also disclose that any source of human nucleic acid can be used, for example, blood and lymphoblostoid cell lines (See column 6, lines 9-14) as recited in

the limitations of claim 50. Johnston-Dow et al. further indicate that HLA typing is performed routinely in connection with many medical indications, the study of auto-immune disease and the determination of susceptibility to infectious disease (See column 1, lines 57-62). This teaching suggests the limitations of claims 36-38 in that the pathogen will be from a virus, prokaryote and eukaryote, the presence of the given target polynucleotide indicates the presence of the genetic disease or a specific allele which can indicate serotype.

It would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to apply the sequencing method of Johnston-Dow et al. because the method of Johnson-Dow et al. is applied to the locus-specific nucleic acid amplification followed by sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37).

The response argues that as discussed above in connection with claim 26, Wittwer would not have taught or suggested the limitation "combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide". Since there is no specific argument for this rejection, as discussed in section 1 regarding this limitation set forth above, with the same reasons as set forth in section 1, the rejection is maintained.

3. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. (6,174,670, issued January 16, 2001) as applied to claims 26, 28-35, 39-40, 43-45 and 47-50 above, and further in view of Lukhtanov et al. (6,790,945, issued September 14, 2004).

The teachings of Wittwer et al. are set forth section 3 above. Wittwer et al. do not disclose using a minor groove binding molecule as a fluorescent indicator.

Lukhtanov et al. disclose oligonucleotide probes containing a minor groove binding molecule (See the abstract). The invention relates to oligonucleotide-quencher-fluorescent-dye conjugates having improved characteristics and to reagents suitable for incorporating novel quencher and fluorescent dye moieties into oligonucleotide (See column 1, lines 1-18 and column 4, lines 46-57).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the minor groove binding molecule of Lukhtamov et al. because Lukhtamov et al. indicate that the reagents used for labeling oligonucleotide overcome the unfavorable

characteristics (See column 4, lines 28-30), for example, mixtures are difficult to separate or unstable during oligonucleotide synthesis or having overlapping emission wavelengths with other desirable reporters (See column 4, lines 24-27). It would have been prima facie obvious to have minor groove binding molecule as a fluorescent indicator for determining the presence and sequence of at least one target polynucleotide in a sample.

The response argues that as discussed above in connection with claim 26, Wittwer would not have taught of suggested the limitation "combining nucleic acid from the sample with at least one set of reaction composition comprising a first reaction composition and second reaction composition, both specific for the at least one target polynucleotide, wherein the first reaction composition comprises amplification primers specific to at least one target polynucleotide and the second reaction composition comprises a fluorescent indicator and amplification primers specific to at least one target polynucleotide". Since there is no specific argument for this rejection, as discussed in section 1 regarding this limitation set forth above, with the same reasons as set forth in section 1, the rejection is maintained.

Summary

4. No claims are allowable.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
August 7, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/8/06